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09/807,504	12/17/2001	Ryszard Kobylecki	687-94	9353

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 09/04/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,504

Applicant(s)

KOBYLECKI, RYSZARD

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,40-43,47-58 and 75-82 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 38,40-43,47-58 and 75-82 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed 7/8/03 in Paper No. 12 is acknowledged and entered. Claims 1-37, 39, 44-46, and 59-74 are canceled by the amendment. Claims 38, 48, and 53-54 are amended by the amendment. Claims 75-82 are added by the amendment.
2. Claims 38, 40-43, 47-58, and 75-82 are pending.

Drawings

3. The drawings were received on 7/8/03. These drawings are acceptable.

Specification

4. A new abstract of the disclosure that is presented on a separate sheet, apart from any other text is acknowledged and entered.

Withdrawn Rejections

5. The previous rejections 35 USC 112, second paragraph, for claims 38-58 have been withdrawn in view of applicant's amendments of claims 38, 48, and 53-54 and cancellation of claims 39, and 44-46.
6. The previous rejections under 35 USC 102(b) as being anticipated by Rohrbach et al. (US Patent 4,218,363) for claims 38, 42, 44, 46-48, and 50-54 have been withdrawn in view of applicant's amendments of claim 38 and argument that the "[a]ctive material are entrapped and held in position by a physical weld (basis for "physical weld" appears at page 12, line 6 of the

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specification). This physical welds results from sintering process, which is used in preferred embodiments of the present invention” (pg. 6, lines 10-15 of the specification).

7. The previous rejections under 35 USC 102(e) as being anticipated by Kobylecki et al. (US Patent 6,153,375; filing date of 5/16/1997) for claims 38-58 have been withdrawn in view of applicant’s amendments of claim 38 and argument that the “[a]ctive material are entrapped and held in position by a physical weld (basis for “physical weld” appears at page 12, line 6 of the specification). This physical welds results from sintering process, which is used in preferred embodiments of the present invention” (pg. 6, lines 10-15 of the specification).

8. Claims 38, 40-43, 47-58, and 75-82 are treated on the merit in this Office Action.

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 112

10. Claims 38, 40-43, 47-58 (*Claims 39, and 44-46 are cancel*), and (*new claims*) 76-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 38 recites a method of synthesis using a porous device. The porous device comprises a body having an internal region which is porous, wherein an active material is entrapped within the internal region.

The specification disclosure does not sufficiently teach the method of synthesis of any compounds using a porous device (e.g. a synthesis of compounds such as biochemical compounds or organic compounds or a synthesis of making particles such as liposomes or hydrogel).

The specification description is directed to the porous device (pg. 3-10) and a method of using a porous device in an "assay" method (pg. 2, lines 14-33 to pg. 3, lines 1-4). This method clearly does not provide an adequate representation regarding method steps for any type of synthesis. The specification examples are drawn to methods of functionalizing resin (e.g. particle). The specification does not teach any method of synthesis using a porous device.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the method of functionalizing resin disclosed by the specification, the skilled artisan cannot envision the method of synthesis using a porous device (e.g. a synthesis of compounds such as oligonucleotide or peptidomimetic compounds or organic compounds or a synthesis of making particles such as liposomes or hydrogel). Adequate written description

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requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the method of the instant claims claimed a method of synthesis using a porous device. The specification does not teach the method of synthesis of any compounds using a porous device (e.g. a synthesis of compounds such as biochemical compounds or organic compounds or a synthesis of making particles such as liposomes or hydrogel). Therefore, only the method of functionalizing resin, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

Response to Arguments

11. Applicant's argument(s) directed to the above rejection under 35 U.S.C. 112, first paragraph (written description), for claim(s) 38, 40-43, 47-58 (*Claims 39, and 44-46 are cancel*),

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and 76-82 (*new claims*) have been fully considered but they are not persuasive for the following reasons.

Applicant alleges that “[t]he specification discloses that a wide range of reactions can be carried out on the plugs, and illustrates the fact that the plugs can be used in situations where the resin alone was previously used.” Applicant further briefly described the examples that illustrate “[t]hat the plugs can be used in a wide range of synthetic methods”. “[E]xample 1 and 2 in the specification show that the plugs are stable in situations encountered during chemical reactions, for example boiling in solvents and centrifugation. Examples 3 and 4 describe a range of reactions that can be undertaken on the plugs. Examples 5 to 7 show how other solid supported reactions can be undertaken on the plugs. Example 8 and 9 describe the preparation of peptides. Examples 10 and 11 show that certain other reactions such as the Suzuki and the Mitsunobu reactions can be undertaken on the plugs. Subsequent examples show that oxidation and reduction reactions can be carried out on the plugs and polypeptides can be prepared on the plugs. Examples 17 to 19 show how libraries of compounds can be prepared using the plugs.” Therefore, “[i]t is clear that the inventor had possession of the claimed invention.”

Applicant's arguments are not convincing since the specification does not teach the method of synthesis of *any* compounds using a porous device (e.g. synthesis of chemical compounds such as organic, inorganic, and biochemical compounds such as DNA synthesis or protein synthesis). The examples in the specification disclose “a wide range of reactions” for the porous device (e.g. plug) such as attachment of the linker to the ‘plug’ (e.g. example 3, examples 5 to 7, and examples 14 to 16), attachment of peptide to the ‘plug’ (e.g. examples 8 to 9), functionalizing the “linker” of the “plug” by methods such as Mitsunobu esterification reaction,

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Suzuki coupling reaction, oxidation, and reduction (e.g. example 4, and examples 10-12). The specification also provided examples of the stability of the 'plug' under certain conditions such as heat (e.g. example 1), centrifugation (e.g. example 2), and washing to remove dye (e.g. example 13). These examples do not teach the method of synthesis of *any* compounds using the 'plug' but rather methods of making the 'plug' (e.g. attaching a linker or peptide to the 'plug'). Examples 17 to 19 disclose method of split-pool synthesis of a library of organic compounds such as biaryl derivatives of example 18. However the method steps of the presently claimed method, which recite "*a method of synthesis comprising the step of contacting said porous device with a first reagent under conditions which cause said first reagent to react with said active material, so that a bond is formed between the active material and said first reagent or fragment thereof*", is incomplete with regard to the method disclosed in examples 17 to 19 for the method steps would result in attachment of *any* compound to the 'plug' and not a method of synthesizing *any* compounds. Further, the full breath of the presently claimed method (e.g. the method of synthesizing *any* compounds such as inorganic, DNA, and protein) is not disclosed by the specification and the examples 17 to 19. Therefore, it is unclear that the inventor has possession of the presently claimed method.

Claim Rejections - 35 USC § 102

12. Claims 38, 40-43, 47-56 (*Claims 39, and 44-46 are cancel*), 58, (*new claims*) 76-77, 79, and 81-82 are rejected under 35 U.S.C. 102(b) (*a typographical error was made in the previous action in that the rejection state that it is 35 U.S.C. 102(a) instead of 35 U.S.C. 102(b)*) as being anticipates by BIOSEPRA INC. (WO 98/41534).

The instant claimed method of synthesis using a porous device. The porous device comprises an internal region, which is porous, and an active material, wherein an active material is entrapped within the internal region. The active material includes a linker. The method steps comprise contacting the porous device with a reagent, wherein the reagent is bonded to the active material and cleaving the compound from the active material.

BIOSEPRA INC. disclosed a method for solid phase synthesis of molecules using a porous ceramic solid support (porous device) (pg. 6, lines 7-16). The porous ceramic solid support comprises pore-filled ceramic particles (internal region) (pg. 6, lines 7-16; pg. 11, lines 17-25). The method steps comprise of derivatizing a three-dimensional polymer network within interior channels of the pore-filled ceramic particles with one or more appropriate chemical functionalities (active material), which permit attachment of an organic molecule (reagent) to the three-dimensional polymer network. The method step of subjecting the organic molecule to reactions, which result in synthesis of said molecules. The method step further comprise of coupling a compatible or appropriate linker to the functionality, coupling a first organic molecule such as amino acid or peptidomimetic moiety to the linker, and coupling one or more additional amino acid or peptidomimetic moiety to the first amino acid or peptidomimetic moiety. Then cleaving the resulting elongated polypeptide chain or peptidomimetic product from the porous ceramic solid support (pg. 6, lines 17-27; pg. 18, lines 15-20). Therefore, the method of BIOSEPRA INC. anticipates the presently claimed invention.

Further, BIOSEPRA INC. discloses "some of the pores that permeate the interior of the particle are filled with an insoluble polymeric material. Exemplary insoluble polymeric

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materials that can be employed include polymer resins” (pg. 15, lines 23-29) (refer to new claim 76-77, 79, and 81-82).

Response to Arguments

13. Applicant's argument(s) directed to the above rejection under 35 USC 102(b) as being anticipated by BIOSEPPRA INC. (WO 98/41534) for claims 38, 40-43, 47-56 (*Claims 39, and 44-46 are cancel*), 58, and 76-82 (*new claims*) were considered but they are not persuasive for the following reasons.

Applicant contends that “[B]IOSEPPRA INC. does disclose a porous device wherein a multiplicity of particles of an active material are entrapped and held in position by a physical weld (basis for “physical weld” appears at page 12, line 6 of the specification). This physical weld results from sintering process, which is used in preferred embodiments of the present invention. During the sintering, there is a softening of the inert material which causes fusion of particles thereof, thereby forming a network, which then holds the active material in position.” Additionally, applicant argues that “[C]laim 75 is distinguished over Biosepra on the basis that it describes an inert material which is a thermoplastic, and this is not disclosed in Biosepra”.

Applicant's arguments are not convincing since Biosepra do disclose “*a porous device wherein a multiplicity of particles of an active material are entrapped and held in position by a physical weld*”. BIOSEPPRA INC. disclosed a method for solid phase synthesis of molecules using a porous ceramic solid support (porous device) (pg. 6, lines 7-16). The pores of the porous ceramic solid support comprise particles such as polymeric resins (pg. 15, lines 23-29). BIOSEPPRA INC. define “The term “ceramic” is art recognized and refers to a solid, refractory material produced by baking or firing of one or more essentially inorganic substances, e.g.,

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preferably formed simultaneously, or subsequently matured, by the action of heat" (e.g. physical weld). Thus the method for solid phase synthesis of molecules using a porous ceramic solid support BIOSEPRA INC. anticipates the presently claimed method of synthesis using a porous device.

Additionally, applicant argument with regard to the new claim 75 is considered moot since the new claim 75 *not* rejected by BIOSEPRA INC. (WO 98/41534).

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 38, 40-43, 47-58, and 75-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dower et al. (US Patent 5,770,358) and Sucholeiki et al. (US Patent 5,834,121).

Dower et al. disclose a method for synthesizing synthetic oligomer (Abstract; col. 4, lines 66-67). The method comprise of a single oligomer sequence (first reagent) being bound to a solid support (active material) by means of a linker (col. 8, lines 48-67 to col. 9, lines 1-14). The solid support comprise of materials such as colloidal metal particles (col. 11, lines 31-45).

The method of Dower et al. does not expressly disclose that the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material.

Sucholeiki et al. disclose a “[c]omposite bead comprises 1) a plurality of primary beads or particles, each of which is a polymer-coated or polymer-encapsulated metal oxide that has inducible magnetic properties, and 2) a mesh or matrix comprising of a thermoplastic polymer resin that is microporous, and which is capable of swelling or expanding in organic solvent, wherein the primary beads are randomly distributed throughout the matrix. The composite bead is essentially spherical in shape and has an uneven, undulating surface” (col. 2, lines 43-51). The bead would “[p]rovides a support system which retains its magnetic properties, has a high loading capacity, and maintains availability of reaction sites, even though it swells and contracts depending upon the solvent and temperature conditions to which it is exposed’ (col. 2, lines 23-42).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material as taught by Sucholeiki et al. in the method of Dower et al. One of ordinary skill in the art would have been motivated to include the solid support (active material) is entrapped within a porous support and the porous support is a thermoplastic inert material in the method of Dower et al. for the advantage of providing a support system that has a high loading capacity and maintains availability of reaction sites for chemical synthesis where rapid separation of products from reactants in solution is desired (Sucholeiki: col. 2, lines 23-42) since both Dower et al. and Sucholeiki et al. disclose method of

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organic synthesis bound to a solid support (Dower: col. 8, lines 48-67 to col. 9, lines 1-14; Sucholeiki: col. 3, lines 49-59).

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct

August 26, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER